

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (withdrawn) A medical device for treating a wound, comprising:
 - (a) sealing means for preventing external substances from entering the wound by contacting the skin around the wound; and
 - (b) gap-filling means carried by the sealing means and adapted to contact the skin around about the wound and sealingly fill gaps between the skin around the wound and the sealing means in a substantially air-tight manner when the gap-filling means is placed between the sealing means and skin.
2. (withdrawn) The medical device of claim 1, wherein the gap-filling means is substantially free of memory, whereby, when it is changed from its original shape and molded into gaps between the sealing means and skin to have a new shape, it will retain the new shape and not return to its original shape.
3. (withdrawn) The medical device of claim 1, wherein a removable cover sheet is provided, carried by the sealing means and sandwiching the gap-filling means between the sealing means and the cover sheet.
4. (withdrawn) The medical device of claim 3, wherein the cover sheet comprises a release liner.
5. (withdrawn) The medical device of claim 2, wherein an adhesive is provided, in addition to said gap-filling means, for adhering the sealing means to the skin.
6. (withdrawn) The medical device of claim 5, wherein a removable cover sheet is provided, carried by the sealing means and sandwiching the gap-filling means between the sealing means and the cover sheet, wherein the cover sheet comprises a release liner, and wherein the adhesive releasably secures the release liner to the sealing means.
7. (withdrawn) The medical device of any one of claims 1-2, including suction means in

communication with the sealing means, for providing a suction to the wound, to promote wound drainage.

8. (withdrawn) A medical device for treating a wound by promoting wound drainage comprising:

- (a) an enclosure for placement over the wound and engaging the surface of skin around the wound, the enclosure being substantially non-protruding away from the skin surface around the wound;
- (b) the enclosure including an openable and reclosable cover means for access to the wound;
- (c) with the cover means being substantially air-tight when closed; and
- (d) suction means communicating with said enclosure, for applying suction to the wound.

9. (withdrawn) The medical device of claim 8, wherein the suction means comprises means for applying continuous suction to the wound and means for varying the level of suction applied to the wound.

10. (withdrawn) The medical device of claim 8, wherein the enclosure is substantially flexibly conformable to the surface around the wound.

11. (withdrawn) The medical device of claim 8, wherein the enclosure includes an opening that has a peripheral zone adapted to be applied to the skin surface around the wound, leaving an enclosure area inside the peripheral zone of a predetermined size, greater than the area of the wound to which the enclosure is to be applied.

12. (withdrawn) The medical device of claim 8, wherein the enclosure comprises a flexible thermoplastic film.

13. (withdrawn) The medical device of claim 8, wherein the enclosure includes a flexible extending means, wherein the volume beneath the enclosure can be reduced when suction is applied by the suction means and the extending means collapses close to the skin in response to

suction applied by the suction means.

14. (withdrawn) The medical device of claim 13, wherein the extending means is bellows-like.

15. (withdrawn) The medical device of claim 8, wherein the cover means includes at least one connectable and disconnectable peripheral portion of said enclosure.

16. (withdrawn) The medical device of claim 15, wherein said cover means is adhesively connectable and disconnectable from the rest of said enclosure.

17. (withdrawn) The medical device of claim 15, wherein said cover means is connectable and disconnectable from the rest of said enclosure by means of a mechanical interlock.

18. (withdrawn) The medical device of claim 8, wherein the cover means is both adhesively disconnectible and mechanically disconnectible from the rest of said enclosure.

19. (withdrawn) The medical device of claim 8, including gap-filling means carried by the enclosure for engaging the skin around the wound, for facilitating an airtight relationship between the enclosure and skin disposed around the wound.

20. (withdrawn) The medical device of claim 8, including removable semi-rigid frame means carried by said enclosure, for facilitating shape-retention of said enclosure until the enclosure is applied to skin disposed about the wound.

21. (withdrawn) The medical device of claim 20, wherein said frame means is connected to said enclosure by pre-formed perforation means in said enclosure.

22. (withdrawn) The medical device of claim 13, wherein the extending means connects the cover means to the portion of the enclosure that engages the surface of the skin around a wound, whereby the cover means can be opened and closed when the cover means is moved away from the surface of the wound.

23. (currently amended): A medical device for treating a wound of a patient, the wound comprising a wound cavity having sides, an interior and at least one wound axis extending

generally parallel to the skin of the patient contiguous with the wound cavity, said device being arranged for encouraging the contraction of the wound along ~~said~~ the at least one wound axis, comprising:

(a) an enclosure for engaging the skin of the patient over and around the wound and having an opening for communication with the interior of the wound cavity ~~a source of suction arranged for applying continuous suction to the wound;~~

(b) ~~an enclosure coupled to said~~ a separate anisotropic wound packing formed of ~~at least one roll~~ plural rolls of gauze, each of said at least one roll rolls having a longitudinal axis and at least one radial axis and comprising plural spiral layers wound about said longitudinal axis, said plural rolls of said wound packing being arranged to be tailored to individual wound cavity shapes and placed in the interior of the wound cavity with said at least one radial axis of each roll facing a side of the wound cavity and extending parallel to the at least one wound axis[.];

(c) an enclosure coupled to said wound packing, said enclosure being arranged to be separately placed over said wound packing after said wound packing has been placed in the interior of the wound cavity to produce an enclosed interior space in the wound in which said wound packing is located ~~source of suction and arranged for maintaining continuous suction on the wound by engaging the skin of the patient around the wound;~~ and

(~~e~~) (d) a source of suction coupled to said enclosure to directly apply continuous suction via said opening in said enclosure to said enclosed interior space to draw fluid from the wound out of the enclosure, while causing ~~cause~~ said rolls of said wound packing ~~an anisotropic wound packing formed of a spirally wound cylindrically configured winding of gauze arranged to preferably collapse inward along said at least one in radial axis directions, said wound packing being arranged to be placed in the wound to encourage preferential the contraction of the wound along the at least one wound axis when continuous suction is applied to the wound to impose a controlled directional strain on wound tissue along said at least one radial axis at an amplitude for optimizing closure of the wound, said wound packing also serving to prevent pooling of fluid in the wound cavity.~~

24. (canceled)

25. (canceled)

26. (canceled).

27. (canceled)

28. (previously amended) The medical device of claim 23, wherein said enclosure is arranged to create a substantially air-tight seal with the skin of the patient.

29. (canceled)

30. (withdrawn) A medical device for treating a wound by promoting wound drainage, comprising:

(a) suction means for applying continuous suction to the wound;

(b) sealing means for maintaining suction on the wound by engaging the skin around the wound;

(c) including leak detection means operationally disposed between the suction means and the sealing means.

31. (withdrawn) The medical device of claim 30, wherein the leak detection means is of the bubble detector type, having a liquid in a closed container, with the suction means connected to the container above a liquid level in the container and a connection from below the liquid level in the container to the sealing means, whereby a leak in the system will allow visible bubbles of airflow through the liquid in the container.

32. (withdrawn) The medical device of claim 30, wherein a discharge container for liquid suctioned from the sealing means is operationally disposed between the sealing means and leak detection means.

33. (withdrawn) The medical device of claim 7, wherein said suction means is a manual suction means.

34. (canceled)

35. (withdrawn) The medical device of claim 8, wherein said suction means comprises first regulator means for applying a constant first level of suction or pressure and at least an additional second regulator means for periodically applying a second level of suction or pressure, to said enclosure.

36. (withdrawn) The medical device of claim 35, including check valve means between said first regulator means and said enclosure and between said second regulator means and said enclosure.

37. (withdrawn) The medical device of claim 9, wherein the enclosure is substantially flexibly conformable to the surface around the wound and is substantially non-protruding away from the skin surface around the wound when applied to the surface around the wound, wherein the enclosure includes an opening that has a peripheral zone adapted to applied to the skin surface around the wound, leaving an enclosure area inside the peripheral zone of a predetermined size, greater than the area of the wound to which the enclosure is to be applied, wherein the enclosure comprises a flexible thermoplastic film, wherein the enclosure includes a flexible bellows-like means, wherein the volume beneath the enclosure can be reduced when suction is applied by the suction means and the bellows-like means folds close to the skin in response to suction applied by the suction means, wherein the cover means includes at least one connectable and disconnectable peripheral portion of said enclosure, including gap-filling means carried by the enclosure for engaging the skin around the wound, for facilitating an air-tight relationship between the enclosure and skin disposed around the wound, wherein the enclosure comprises a sealing means, wherein the gap-filling means is substantially free of memory, whereby, when it is changed from its original shape and molded into gaps between the sealing means and skin to have a new shape, it will retain the new shape and not return to its original shape, wherein a removable cover sheet is provided, carried by the sealing means and

sandwiching the gap-filling means between the sealing means and the cover sheet, wherein the cover sheet comprises a release liner, wherein an adhesive is provided, in addition to said gap-filling means, for sealing the sealing means to the skin, including removable semi-rigid frame means carried by said enclosure, for facilitating shape-retention of said enclosure until the enclosure is applied to skin disposed about the wound, wherein said frame means is connected to said enclosure by pre-formed perforation means in said enclosure, including wound packing means, for placement into the wound, for absorbing liquids from the wound to prevent substantial pooling of liquids in the wound, said wound packing means being of the anisotropic type and having at least one predetermined direction of contraction in response to said suction, wherein the packing means comprises gauze, wherein the packing means comprises at least one generally cylindrical gauze roll configuration having a generally longitudinal axis and radial axes, to be disposed in the wound with it's longitudinal axis facing outside the wound and it's radial axes facing sides of the wound, including leak detection means operationally disposed between the suction means and the sealing means, and wherein the leak detection means is of the bubble detector type, having a liquid in a closed container, with the suction means connected to the container above a liquid level in the container and a connection from below the liquid level in the container to the sealing means, whereby a leak in the system will allow visible bubbles of airflow through the liquid in the container.

38. (withdrawn) The method of detecting a leak in a wound enclosure apparatus comprising the steps of:

- (a) connecting a suction means to the wound enclosure apparatus; and
- (b) connecting a flow indicating means in communication with the suction means, to determine by the flow indicated if a leak is present.

39. (currently amended): A method of controlling the direction of contraction of a wound of a patient, the wound comprising a wound cavity having sides, an interior and at least one wound axis extending generally parallel to the skin of the patient contiguous with the wound cavity, said method comprising the steps of:

(a) providing ~~an~~ a separate anisotropic wound packing formed of ~~at least one roll~~ plural rolls of gauze, each of said at least one roll rolls having a longitudinal axis and at least one radial axis and comprising plural spiral layers wound about said longitudinal axis, said plural rolls of said wound packing being arranged to be tailored to individual wound cavity ~~a spirally wound cylindrically configured winding of gauze arranged to preferably collapse inward in radial directions;~~

(b) placing said anisotropic wound packing in said wound cavity with said at least one radial axis of each roll facing a side of the wound and extending parallel to the at least one wound axis ~~in a predetermined orientation~~ to allow a controlled strain to be imposed on the wound tissue;

(c) providing a separate enclosure engaging the skin of the patient over and around the wound, said enclosure having an opening in communication with the interior of the wound;

(d) sealing said wound with said anisotropic wound packing therein to produce an enclosed interior space in the wound in which said wound packing is located contiguous with said wound; and

(e) providing a source of suction coupled to said enclosure to directly apply continuous suction via said opening in said enclosure to said enclosed interior space to draw fluid from the wound out of the enclosure, while causing said rolls of ~~and said wound and maintaining suction therein to cause~~ said wound packing to preferably collapse inward along said at least one radial axis when continuous suction is applied to the wound to impose a controlled directional strain on wound tissue along said at least one radial axis at an amplitude for optimizing closure of the wound, said wound packing also serving to prevent pooling of fluid in ~~to encourage the contraction of the wound cavity along the at least one wound axis.~~

40. (withdrawn) The medical device of claim 1, wherein the enclosure includes an openable and reclosable cover means for access to the wound.

41. (withdrawn) A method for treating a wound comprising: (a) applying a sealing means to the wound to prevent external substances from entering the wound by contacting the skin around the wound; and (b) providing a gap-filling means carried by the sealing means and contacting the skin about the wound with the gap-filling means and sealingly filling gaps between the skin around the wound and the sealing means in a substantially air-tight manner with the gap-filling means placed between the sealing means and the skin.

42. (withdrawn) The medical device of claim 8, wherein said suction means comprises a computer controlled device capable of providing alternating and variable pressures and suction based upon an algorithm.